Course Outline: Medical Device Development Process

Course number:	BMDE 656
Term:	Winter
Year:	2025
Course pre-requisite:	None
Course co-requisite(s):	None
Course restrictions(s):	None
Course schedule:	TBD
Number of credits:	3
Course location:	TBD

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Course Overview

Today's development of medical devices must be performed following existing standards such as ISO 13485:2016 for Europe, 21CFR 820 Quality System Regulation of the FDA (U.S. Food & Drug Administration), and MDSAP (international Medical Device Single Audit Program). These regulations and standards ensure that medical devices are developed in a controlled manner to ensure efficacy and safety for the patient and user. The development projects are milestone-driven and follow a structured development path.

Overview of all the development steps of a medical device, from a "back-of-the-napkin" idea or concept to subsequent use in humans. Discussion of the development of an existing medical device, review of all steps of the design process, including production of the required documentation in order to be able to complete a submission to a regulatory agency.

Learning Outcomes:

By the end of the course, students should be able to:

1) Describe how to initiate development of a new medical device. While this is not a business development course, students should understand the minimum requirements before pursuing development of a new medical device, such as whether the device addresses an unmet clinical need, what are current or competitive products on the market, what is the intellectual property landscape, etc..
2) Evaluate the feasibility/prototyping phase: Can it be built? Will it be manufacturable at a price the market is willing to pay?

3) Collect user needs and establish design inputs - the most important phase of the project. Students should understand how to produce a *Marketing Product Requirement Specification* (MPRS) document and a *Design Inputs and Design Outputs* (DI/DO) *matrix* (also called a *Design Traceability Matrix - DTM*). These are requirements of the FDA's *Quality System Regulation* (QSR) and ISO 13485.

4) Create a Risk Management File. Students will learn how to use risk analysis tools such as Failure *Modes and Effects Analysis* (FMEA) to assess risk related to design elements, manufacturing processes, and usability, then mitigate them to achieve a positive risk/benefit. Students should also understand the requirements of ISO 14971 Risk Management for Medical Devices, and how risk management is part of the daily life of medical device development teams and is active throughout the lifecycle of the medical device.

5) Demonstrate the development of a medical device under the strict guidelines of Design Controls, including design with full traceability, how to control document revisions during development phases, and how build a Design History File that documents all the different steps and iterations of the medical device development and is a regulatory requirement.

6) Build an *Engineering Characterization Test* (ECT) Protocol based on the technical requirements of the DI/DO matrix, applicable regulatory standards, findings from risk management activities, and other identified potential issues that need to be tested. These include biocompatibility testing, transport simulation, usability testing, performance testing, aging studies, and sterilization validation.

7) Determine when and how to perform a *Design Freeze* and the steps to get there, including identifying every design input identified in the DI/DO matrix in a manner that ensures a verifiable corresponding output.

8) Understand how to perform *Design Verification* (DV) Testing to ensure all design inputs have been verified to an acceptable level, using risk-based confidence and reliability levels, including how to determine sample sizes based on risk, and how to release the design in Document Control once DV Testing has been performed. Understand the difference between *Design Verification* and *Design Validation*.

9) Understand *Document Control* and the roles of Quality Assurance within the design teams.

10) Describe the requirements of process validation and the link between process-related risk analysis and the process validation requirements.

11) Described at a high level the different regulatory filing methods – while this is not a Regulatory Affairs (RA) course nor is it a Quality Assurance (QA) course, students should understand the technical implications of the chosen path to market.

12) Understand possible "shortcuts" that can be taken, while staying in compliance with the regulations, so the device can reach human clinical trials faster (usage in humans is the goal).

Instructional Method

All students will be exposed to one medical device. The device will be reverse engineered to create a full Design History File comprising of documents that result from all the development steps of a medical device. For course assignments, students will be asked to create documents to support the design process.

<table>
<tr><th>Week</th><th>Topics</th><th>Assignments / To-Do</th></tr>
<tr><td>1</td><td rowspan="3">Introduction – André Tremblay
Introduction to the lecture team
Introduction and overview of the development process of a medical device.
Introduction to a medical device that will be reverse engineered to create its design dossier by all students. Overview of possible extra features that can be added to the device (e.g., to improve the device or to allow it to treat something else).
Introduction on how to start a project (what is required).
Introduction to ISO 13485, 21CFR 820, and MDSAP.
Introduction to medical device classification for the 3 important regions that this course will discuss: Europe, USA, and Canada.
Prototyping and Feasibility Phase – André Tremblay
Brainstorming techniques
Defining user needs using the Marketing Product Requirements and Specifications template and what the MPRS should entail.
Conceptual differences between user wants, user needs, and design inputs
Design input generation process
Transforming the contents of the MPRS into design inputs using a Design Input/Design Output (DI/DO) matrix.</td><td>Week 1 - Tasks
Fill out personal information form – Complete in class</td></tr>
<tr><td>2</td><td>Week 2 - Tasks
Team assignment – Complete in class
Get assigned device – Complete in class
Meet with your team before next class.
Week 2 – Assignment 1
Brainstorm potential improvements to the assigned device.
Due by next class.</td></tr>
<tr><td>3</td><td>Week 3 – Assignment 2
Complete MPRS on the assigned product.
Due by next class.</td></tr>
<tr><td>4</td><td>Concept Phase Closure, Start of Planning and Development Phase and Design Control – André Tremblay
Establish a Design History File (DHF). Students will build their own DHF that will be populated as design activities progress.
Overview of the Standard Operating Procedure (SOP) for Design Control as the “design bible”.
Overview of planning the rest of the design activities up to project submission, in the form of a Design Review presentation, in the last week of class.</td><td>Week 4 – Assignment 3
DI/DO matrix: complete design input column for the assigned product.
Due by next class.</td></tr>
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Week	Topics	Assignments / To-Do

5	**Overview of Basic Design Principles and Solutions – Boby Chu**
	
	• Popular concepts: Design For Manufacturing (DFM), Poke-Yoke, Lean, 6-sigma, Agile
	• Common manufacturing techniques
	
	Design Documentation
	
	• Creating overall specifications for the product
	• Specifying parts and manufacturing procedures
	  ◦ Part specifications and drawings
	  ◦ Work instructions and manufacturing flowcharts
	  ◦ Material selection (sterilization, biocompatibility considerations)
	• Document control
	  ◦ Revision control
	  ◦ Reviews and approvals
	
	Incoming Inspections and Non-Conformities
	
	• How do you know if your parts are good? What to do with bad parts?
	• Overview of quality statistics
	• Handling non-conformities
	  ◦ Non-Conformity Report (NCR)
	  ◦ Corrective and Preventative Actions (CAPA)
		Week 5 – Assignment 4
		
		• Create drawings and specifications for the assigned device.
		• DI/DO matrix: complete design output column for assigned product.
		• Due by next class.

6	**Usability Engineering – Boby Chu** • Overview of usability engineering as per IEC 62366-1:2015 • How usability engineering integrates into the overall design process **Risk Management – Boby Chu**	**Week 6 – Assignment 5** • Create a risk scale appropriate for the assigned product. • Design FMEA: identify functions, failure modes, effects, and assign risk priority number.

Week	Topics	Assignments / To-Do
	• Introduction to risk management as per ISO 14971 and how it integrates into Design Control and the overall design process • Introduction of risk management tools: *Risk Analysis*, *Failure Mode and Effects Analysis* (FMEA), *Fishbone Diagram*, *Fault-Tree Analysis* (FTA) • Deeper dive into types of FMEAs, focusing on design FMEA (dFMEA).	• Identify patient population, intended user profiles, and use environments for the assigned product. • Identify at least 2 hazard-related use scenarios for the assigned product. • Due by next class.

7	**Biocompatibility, Sterilization, and Packaging – Boby Chu**
	• Introduction to biocompatibility
	  ○ Requirements as per ISO 10993
	  ○ Practical design considerations
	• Introduction to sterilization
	  ○ Types of sterilization: ethylene-oxide (EO), irradiation (gamma, electron beam, x-ray), NO_2, steam, etc....
	  ○ Principle of Sterilization Assurance Level and how it is applied
	  ○ Developing sterilization parameters for EO and irradiation
	  ○ Design considerations
	  ○ Practical considerations: New cycle development vs cycle adoption, double sterilization, etc.
	• Packaging design principles
	  ○ Transport, environmental factors, usability considerations
		Week 7 – Assignment 6
		• Provide rationale for sterilization method used in the assigned product.
		• Identify biocompatibility tests applicable to the assigned product.
		• Identify the type of packaging test required for the assigned product.
		• Due by next class.

8	**Engineering Characterization Testing (ECT) and Design Freeze – Teresa Mihalik**	**Week 8 – Assignment 7** • Create Engineering Characterization test plan for the assigned product. • Due by next class.

Week	Topics	Assignments / To-Do
	• Based on MPRS, dFMEA, industry standards and DIDO Matrix, build the test plan to verify the robustness of the device. • Write ECT protocol. The ECT protocol will be the basis for the DV protocol (Development Verification Testing after Design Freeze). • Basic statistics for data analyses, calculating capability to pre-established acceptance criteria. • Design Freeze (milestone) – how and when to Design Freeze, Go/No-Go decision for next project phase. Deliverables including the Device Master Record (DMR), Work Instructions (WI), Lot History Record (LHR), Bill of Materials (BOM). Importantly, ensuring high confidence that Design Outputs meet the Design Inputs and that every requirement of the DIDO Matrix is answered.	
9 10	**Design Verification Testing (DVT) – Teresa Mihalik** • Verifying all Design Outputs meet the requirements of the associated Design Inputs. • Determining the number of samples based on the risk profile of the device as determined through the FMEA and Risk Analysis (e.g., the risks associated with going into the brain or heart are much higher than the stomach – therefore the higher the risks, the larger the sample size). Overview of tables containing sample size requirements based on % Probability and % Reliability and the Risk profile. • The tests performed within the DV testing as follows: ◦ Packaging Testing per ASTM Methods including vibration and drop testing; ◦ Sterile Barrier testing to ensure no damage from Packaging Testing, using Bubble emission or Dye penetration tests, or both; ◦ Biocompatibility Testing per ISO 10993-1. Testing regimes vary based on location and duration in the body; ◦ Accelerated aging testing – to ensure product robustness over time, devices are submitted to accelerated aging which is usually done at high temperatures (between 55°C and 60°C). ◦ Environmental conditioning	**Week 9 – Assignment 8** • Create a Design Verification test plan for the assigned product. • Create one test method. • Due by class 11.
11	**Regulatory Fillings – Teresa Mihalik**	**Week 10 – Assignment 9**

Week	Topics	Assignments / To-Do
	• After DV testing is complete, now is the time to start building/assembling the dossier to present to the different regulatory agencies, such as Health Canada, the European Commission (CE), and FDA (Pre-Market Approval / PMA for high-risk devices, and 510(k) for medium-risk devices). • Discussion of the requirements for different filing strategies depending on the device, including novel devices with no equivalence, new improved devices that can be compared to existing, and families of devices with small changes (e.g., different reaches or different sizes of balloons). We will also look at Compassionate Use filing strategies.	• Complete Verification and Evidence columns of the DI/DO matrix. • Due by next class.
12	**Design Transfer to Production – Boby Chu** • Process Validation • After regulatory filling and depending on the submission type, there is a waiting period where the design documents are transferred to Document Control. We will discuss why everything is transferred, and how new revisions of the device can be developed in parallel (current and accepted industry practices). • Discussion of the semester, final clarifications, and question period.	• Prepare for final presentation. • Due by next class.
13	**Final Presentation** • Present the DHF that your team has compiled. • Presentation will take the form of a Design Review.	

Evaluation

Assignments	**72%**
Assignment 1	5%
Assignment 2	8%
Assignment 3	8%
Assignment 4	10%
Assignment 5	10%
Assignment 6	5%
Assignment 7	8%
Assignment 8	10%
Assignment 9	8%
Final Presentation	**28%**

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